Vifor Pharma and Cara Therapeutics sign US license agreement for IV Korsuva™* to treat dialysis patients with pruritus

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- **Vifor Pharma secures commercial rights for IV Korsuva in non-Fresenius Medical Care dialysis clinics representing approx. 66% of the market, under a profit-sharing arrangement with Cara**
- **Cara will receive a USD 100 million upfront payment and an equity investment of USD 50 million**
- **IV Korsuva aims to address a significant unmet medical need for a highly debilitating disease**
- **NDA submission for IV Korsuva expected in Q4, 2020**

- Cara to Host Conference Call Today at 8:30 am EDT -

STAMFORD, Conn. and ST. GALLEN, Switzerland, Oct. 20, 2020 (GLOBE NEWSWIRE) -- Vifor Pharma and Cara Therapeutics, Inc. (Nasdaq:CARA) today announced that both companies have signed a license agreement for commercialization of Korsuva (difelikefalin) Injection ("IV Korsuva") for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in the US dialysis market for non-Fresenius Medical Care clinics under a Cara 60%, Vifor Pharma 40% profit-sharing arrangement.

"With an established fully dedicated nephrology sales force in the US, Vifor Pharma is an ideal commercialization partner to bring IV Korsuva to dialysis patients across the country," said **Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics**. "In addition, we believe Vifor Pharma's existing relationships with US dialysis providers will provide significant momentum for the launch and adoption of IV Korsuva, if approved. As a result of this agreement, we expect to focus Cara's internal resources on our clinical programs for Oral Korsuva in atopic dermatitis, pre-dialysis CKD and additional pruritic conditions."

"Vifor Pharma has a strong market position and deep expertise in the nephrology space. This agreement further strengthens our US nephrology presence. The Vifor Pharma Group now has the commercialization rights for IV Korsuva in the full dialysis segment by adding all non-FMC dialysis clinics, representing approximately 66% of the US market," said **Stefan Schulze, CEO of Vifor Pharma Group**. "Moderate to severe haemodialysis-associated pruritus is a debilitating condition that impacts up to 40% of dialysis patients around the world and for which there is currently no approved treatment in the US or Europe. IV Korsuva is an important, innovative new therapeutic that has the potential to address this significant unmet need. We remain committed to making IV Korsuva available next year to dialysis patients, who urgently need an effective therapy."

Under the terms of the agreement, Cara will receive an upfront payment of USD 100 million in cash and an equity investment of USD 50 million. In addition, Cara will be eligible to receive an additional equity investment upon US regulatory approval of IV Korsuva, as well as milestone payments dependent on achieving commercial targets, which together could total up to USD 290 million. Additional information regarding the terms of the agreements between Cara and Vifor announced today will be set forth in a Current Report on Form 8-K to be filed by Cara with the U.S. Securities and Exchange Commission on October 20, 2020.

In May 2018, Cara Therapeutics and Vifor Fresenius Medical Care Renal Pharma (VFMCRP) signed an initial agreement that granted the rights to develop and commercialize IV Korsuva for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in hemodialysis and peritoneal dialysis patients worldwide, excluding the US, Japan and South Korea. At that time Cara retained full development and commercialization rights for IV Korsuva for the treatment of CKD-aP in the US except in the dialysis clinics of Fresenius Medical Care North America (FMCNA), where VFMCRP and Cara were to promote IV Korsuva under a profit-sharing arrangement based on net FMCNA clinic sales recorded by Cara. Under the agreement, Cara had sole responsibility to promote IV Korsuva in the US in non-Fresenius Medical Care clinics.

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Conference Call
Cara management will host a conference call today at 8:30 am EDT to discuss the licensing agreement. To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 1891110. A live webcast of the call can be accessed under "Events and Presentations" in the News & Investors section of Cara's website at www.CaraTherapeutics.com. An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care).
Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).
For more information, please visit viforpharma.com

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In two Phase 3 trials, IV KORSUVA has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP). Cara has successfully completed its Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with CKD and is currently conducting Phase 2 trials of Oral KORSUVA in atopic dermatitis and primary biliary cholangitis patients with moderate-to-severe pruritus.

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients with chronic kidney disease undergoing dialysis. Pruritus has also been reported in patients with stage III-V CKD who are not on dialysis. Aggregate, longitudinal, multi-country studies estimate the weighted prevalence of CKD-aP to be approximately 40 percent in patients on dialysis, with approximately 25 percent of patients reporting severe pruritus. The majority of dialysis patients (approximately 60-70 percent) report pruritus, with 30 to 40 percent reporting moderate or severe pruritus.[1,2] Recent data from the ITCH National Registry Study showed that among those with pruritus, approximately 59 percent experienced symptoms daily or nearly daily for more than a year. Given its association with CKD/ESRD, most afflicted patients will continue to have symptoms for months or years, with currently employed antipruritic treatments, such as antihistamines and corticosteroids, unable to provide consistent, adequate relief. Moderate-to-severe chronic pruritus has repeatedly been shown to directly decrease quality of life, contribute to symptoms that impair quality of life (such as poor sleep quality), and is associated with depression.[3] CKD-aP is also an independent predictor of mortality among haemodialysis patients, mainly related to increased risk of inflammation and infections.

References:
1. Pisoni RL, et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrol Dial Transplant. 2006; 21:3495-3505.
2. Ramakrishnan K, et al. Clinical characteristics and outcomes of end-stage renal disease patients with selfreported pruritus symptoms. International Journal of Nephrology and Renovascular Disease. 2014; 7: 1-12.
3. Mathur VS, et al.

Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning plans, strategies and expectations for the future, including statements concerning the potential commercialization of IV KORSUVA by Vifor Pharma, the potential benefits of Vifor Pharma's marketing IV KORSUVA in the United States through arrangement announced today, the potential of IV KORSUVA to address a significant unmet need, the potential equity investment, milestone and profit-sharing payments payable to Cara Therapeutics pursuant to the agreement and the expected timelines for planned regulatory submissions. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of these risks and uncertainties include, but are not limited to, those related to the initiation and conduct of clinical trials, the receipt of data sufficient to support regulatory submissions and required regulatory approvals of KORSUVA, and uncertainties regarding the rate and degree of market acceptance of IV KORSUVA, if approved for marketing, as well as those risks and uncertainties described more fully in Cara's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara's Annual Report on Form 10-K for the year ended December 31, 2019, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Cara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority*.

Source: Cara Therapeutics, Inc.